

K960800



Diagnostics

JUL 26 1996

510(k) SUMMARY

Subject:	Premarket Notification, 510(k) CEDIA® Red Blood Cell Folate (No Boil) Reagent Pack: Safety and Effectiveness Summary
Manufacturer:	Boehringer Mannheim Corporation 2400 Bisso Lane P.O. Box 4117 Concord CA 94524-4117 Phone 1-800-232-3342 Fax 510 674 0782 Boehringer Mannheim Corporation 9115 Hague Road Indianapolis, IN 46256 Phone 1-800-428-5074
Contact:	Mary Koning, Regulatory Affairs Specialist
Date:	23 February 1996
Proprietary Name	CEDIA® Red Blood Cell Folate (No Boil) Reagent Pack
Common Name	Homogeneous Enzyme Immunoassay for the Quantitative Determination of Folate in Red Blood Cells.
Classification Name	Folate Test System
Predicate Device	CEDIA® Red Blood Cell Folate Reagent Pack
Device Description	CEDIA® Technology The CEDIA® Red Blood Cell Folate (No Boil) Reagent Pack to be used in combination with the CEDIA® Folate (No Boil) Assay is an in- vitro homogeneous enzyme immunoassay used for the quantitative determination of folate in red blood cells. The assay is

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Device Description, cont.	<p>based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.</p> <p>Folate specific binding protein, by binding to folate on the enzyme donor will inhibit enzyme reassociation thereby regulating the level of β-galactosidase formed. Folate present in the sample will compete with the folate bound to the enzyme donor subunit for the limited number of specific binding sites further regulating the level of active enzyme formed. Concentrations of folate are directly proportional to the amount of enzyme formed as monitored by the hydrolysis of the substrate o-nitrophenyl-β-D-galactopyranoside (ONPG).</p>	
Intended Use	<p>The CEDIA® Red Blood Cell Folate (No Boil) Reagent Pack to be used in combination with the CEDIA® Folate (No Boil) Assay is a homogeneous enzyme binding assay for the quantitation of folate in red blood cells.</p>	
Statement of Similarities and Differences	<p>The following table outlines the similarities and differences between the BioRad Quantaphase II B12/Folate Radioassay and CEDIA® Red Blood Cell Folate (No Boil) Reagent Pack.</p>	
Parameter	Bio-Rad Quantaphase II® B12/Folate Assay	CEDIA® Red Blood Cell Folate (No Boil) Reagent Pack
Basic Principle	Competitive Protein Binding (CPB)	Competitive Protein Binding (CPB)
Methodology	Radioimmunoassay	Homogeneous Enzyme Immunoassay
Intended Use	Quantitative determination of Folate in human anticoagulated whole blood	Quantitative determination of Folate in human anticoagulated whole blood
Monitoring System	Bound radioactivity ^{57}Co and ^{125}I with the pellet counted	β -galactosidase hydrolysis of ONPG

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Statement of Similarities and Differences, cont.		
Parameter	CEDIA® Red Blood Cell Folate Reagent Pack	CEDIA® Red Blood Cell Folate (No Boil) Reagent Pack
Detection Mechanism	Gamma counter	Spectrophotometer at 415 nm
Reagents	Protein diluent Ascorbic Acid	Human serum albumin based Low calibrator (0 ng Folate/mL) Ascorbic Acid
Sample Type	EDTA	Heparin
Working Concentration of Ascorbic Acid	0.4%	0.2%
Protocol		
Dilution	1:11	1:100
Incubation	90 minutes	20 - 60 minutes
Temperature	20 - 25° C	20 - 25° C
Stability of Ascorbic Acid	Prepare daily.	Stable for 90 days when stored at 2 - 8 °C
Stability of Hemolysate	Sample is stable for 10 days at -20°C	Sample is stable for 24 hours at -20°C
Expected Values	95 - 570 ng/mL	193 - 964 ng/mL

510(k) SUMMARY,
cont.

Statement of Similarities and Differences, cont.								
Parameter	BioRad Quantaphase II® B12/Folate Assay			CEDIA® Red Blood Cell Folate (No Boil) Reagent Pack				
Precision	Intra -assay: Patient Samples			Intra -assay: Patient Samples				
Level	<u>1</u>	<u>2</u>	<u>3</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	
Within-Run (ng/mL)	818	385	290	502.2	481.7	344.4	147.4	
%CV	3.7	6.5	5.2	5.1	4.4	6.0	8.3	
Method Comparison	N/A			versus CEDIA B12/Folate Assay				
Number =				96				
Correlation =				0.96				
Slope =				1.20				
Intercept =				-30.6				
The performance information establishes the basis for substantial equivalence to the predicate device.								